

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A method for preparing a sterile aqueous suspension of ciclesonide suitable for nebulization comprising the steps of:
 - a. providing an aqueous suspension of ciclesonide, containing at least one non-ionic agent for adjusting osmolality, and one or more pharmaceutically acceptable excipients, which one or more excipients are all non-ionic excipients; and
 - b. autoclaving the aqueous suspension provided in (a).
2. (Currently amended) A method for preparing a sterile aqueous suspension of ciclesonide suitable for nebulization comprising the steps of:
 - a. providing an aqueous suspension of ciclesonide, containing at least one non-ionic agent for adjusting osmolality and optionally further pharmaceutically acceptable excipients, which one or more excipients are all non-ionic excipients; and
 - b. autoclaving the aqueous suspension provided in (a).

3. (Previously presented) The method according to claim 1, wherein ciclesonide is selected from the group consisting of [11 β ,16 α (R)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-diene-3,20-dione, mixtures of the compounds [11 β ,16 α (S)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione) and [11 β ,16 α (R)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)-pregna-1,4-diene-3,20-dione in any desired mixing ratio, and mixtures of the compounds [11 β ,16 α (S)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione) and [11 β ,16 α (R)]-16,17-[(cyclohexylmethylene)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-diene-3,20-dione consisting essentially of R epimers.

4. (Previously presented) The method according to claim 1, wherein ciclesonide is selected from the group consisting of ciclesonide, solvates of ciclesonide, physiologically functional derivatives of ciclesonide, solvates of physiologically functional derivatives of ciclesonide and mixtures thereof.

5. (Previously presented) The method according to claim 4, wherein the physiologically functional derivative of ciclesonide is selected from the group consisting of 16 α ,17-(22R)-cyclohexylmethylenedioxy-11 β ,21-dihydroxypregna-1,4-diene-3,20-dione, 16 α ,17-(22S)-cyclohexylmethylenedioxy-11 β ,21-dihydroxypregna-1,4-diene-3,20-dione,

pregna-1,4-diene-3,20-dione, and mixtures thereof in any mixing ratio.

6. (Previously presented) The method according to claim 1, wherein the mean particle size of ciclesonide is less than 12 μ m.

7. (Previously presented) The method according to claim 2, wherein the non-ionic agent for adjusting the osmolality is selected from the group consisting of mannitol, glycerol, glucose, lactose, trehalose, sucrose, propylene glycol, sorbitol, xylitol, polyethylene glycol, ethanol, isopropanol, cyclodextrins, derivatives of cyclodextrins and mixtures thereof.

8. (Previously presented) The method according to claim 7, wherein the agent for adjusting the osmolality is selected from the group consisting of mannitol, glycerol, glucose and mixtures thereof.

9. (Previously presented) The method according to claim 1, wherein the suitable excipients are selected from the group consisting of agents for adjusting osmolality, suspending agents, agents for modifying pH of the suspension, chelating agents, preservatives and mixtures thereof.

10. (Previously presented) The method according to claim 2, wherein the suitable excipients are selected from the group consisting of suspending agents, agents for modifying pH of the suspension, chelating agents, preservatives and mixtures thereof.

11. (Cancelled)

12. (Previously presented) The method according to claim 9, wherein an agent for modifying the pH of the suspension is present as excipients, which is an organic acid selected from the group consisting of citric acid, tartaric acid, lactic acid and mixtures thereof.

13. (Previously presented) The method according to claim 9, wherein the suspending agent is selected from the group consisting of polysorbates, tyloxapol, poloxamers, poloxamines, polyoxyethylene castor oil derivatives, phospholipids, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, polyvinylpyrrolidone, polyvinylalcohol and mixtures thereof.

14. (Previously presented) The method according to claim 13, wherein the suspending agents are polyoxyethylene sorbitan fatty acid esters.

15. (Previously presented) The method according to claim 1, comprising the steps of

- a. dissolving the non-ionic excipients or excipients in water;
- b. optionally filtering the solution;
- c. homogeneously suspending ciclesonide within the solution and
- d. autoclaving the aqueous suspension provided in (c).

16. (Previously presented) The method according to claim 2, comprising the steps of

- a. dissolving the non-ionic agent for adjusting the osmolality and optionally other excipients in water;
- b. optionally filtering the solution;
- c. homogeneously suspending ciclesonide within the solution; and
- d. autoclaving the aqueous suspension provided in (c).

17. (Previously presented) The method according to claim 1, wherein autoclaving is carried out at a temperature above 90°C.

18. (Previously presented) The method according to claim 17, wherein autoclaving is carried out at a temperature above 120° C.

19. (Previously presented) The method according to claim 17, wherein autoclaving is carried out at 121°C for at least 15 minutes.

20. (Previously presented) The method according to claim 1, wherein the sterile aqueous suspension of ciclesonide suitable for nebulization has an osmolality in the range of 225- 430 mosmol/kg.

21. (Withdrawn) A sterile aqueous suspension of ciclesonide suitable for nebulization containing one or more pharmaceutically acceptable excipients, which one or more excipients are all non-ionic excipients.

22. (Withdrawn) A sterile aqueous suspension of ciclesonide suitable for nebulization containing at least one non-ionic agent for adjusting osmolality and optionally further pharmaceutically acceptable excipients.

23. (Withdrawn) The sterile aqueous suspension according to claim 21, having an osmolality in the range of 225- 430 mosmol/kg.

24. (Withdrawn) The sterile aqueous suspension according to claim 21, wherein the ciclesonide has a mean particle size of less than 12 μ m.

25. (Withdrawn) The sterile aqueous suspension according to claim 22, wherein the non-ionic agent for adjusting the osmolality is selected from the group consisting of mannitol, glycerol, glucose, lactose, trehalose, sucrose, propylene glycol, sorbitol, xylitol, polyethylene glycol, ethanol, isopropanol, cyclodextrins, derivatives of

cyclodextrins and mixtures thereof.

26. (Withdrawn) The sterile aqueous suspension according to claim 25, wherein the agent for adjusting the osmolality is selected from the group consisting of mannitol, glycerol, glucose and mixtures thereof.

27. (Withdrawn) The sterile aqueous suspension according to claim 21, wherein the suitable excipients are selected from the group consisting of agents for adjusting osmolality, suspending agents, agents for modifying pH of the suspension, chelating agents, preservatives and mixtures thereof.

28. (Withdrawn) The sterile aqueous suspension according to claim 22, wherein the suitable excipients are selected from the group consisting of suspending agents, agents for modifying pH of the suspension, chelating agents, preservatives and mixtures thereof.

29. (Withdrawn) The sterile aqueous suspension according to claim 22, wherein suitable excipients are non-ionic excipients.

30. (Withdrawn) The sterile aqueous suspension according to claim 27, wherein an agent for modifying the pH of the suspension is present as an excipient which is an organic acid selected from the group consisting of citric acid, tartaric acid, lactic acid

and mixtures thereof.

31. (Withdrawn) The sterile aqueous suspension according to claim 27, wherein the suspending agent is selected from the group consisting of polysorbates, tyloxapol, poloxamers, poloxamines, polyoxyethylene castor oil derivatives, phospholipids, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, polyvinylpyrrolidone, polyvinylalcohol and mixtures thereof.

32. (Withdrawn) The sterile aqueous suspension according to claim 31, wherein the suspending agents are polyoxyethylene sorbitan fatty acid esters.

33. (Withdrawn) An aqueous suspension of ciclesonide for administration by nebulization, wherein the concentration of ciclesonide within the suspension for nebulization is in the range of 0.005% to 0.5% (w/v).

34. (Withdrawn) The aqueous suspension according to claim 21, wherein the ciclesonide has a mean particle size of less than 12 μ m.

35. (Withdrawn) The aqueous suspension of ciclesonide according to claim 33, which is a sterile suspension.

36. (Withdrawn) The sterile aqueous suspension according to claim 21 for administration by nebulization, wherein the concentration of ciclesonide within the suspension for nebulization is in the range of 0.005% to 0.5% (w/v).
37. (Withdrawn) The sterile aqueous suspension according to claim 21 containing as excipients mannitol and polysorbate or glycerol and polysorbate.
38. (Withdrawn) The sterile aqueous suspension according to claim 37, additionally containing hydrochloric acid or citric acid.
39. (Withdrawn) A method for the prophylaxis or treatment of a clinical condition in a patient for which a glucocorticosteroid is indicated, which comprises administration of a therapeutically effective amount of a sterile aqueous suspension of ciclesonide according to claim 21.
40. (Withdrawn) The method according to claim 39, wherein the clinical condition is asthma the patient is a child and the treatment is a continuous treatment regimen and the sterile aqueous suspension of ciclesonide is administered by nebulization.
41. (Withdrawn) A drug product comprising a sealed container containing a sterile aqueous suspension according to claim 21, and a label indicating administration by nebulization in a continuous treatment regimen.